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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,170	12/14/2001	Li Pan	(DI-5762) 112713-144	6401
29200	7590	03/29/2004	EXAMINER	
BAXTER HEALTHCARE CORPORATION			GAKH, YELENA G	
RENAL DIVISION				
1 BAXTER PARKWAY			ART UNIT	PAPER NUMBER
DF3-3E			1743	
DEERFIELD, IL 60015			DATE MAILED: 03/29/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,170	PAN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION IS:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 March 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-53 is/are pending in the application.
4a) Of the above claim(s) 10-27 and 31-53 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-9 and 28-30 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 27 February 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____.
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date 01/08/04. 6) Other: ____.

DETAILED ACTION

1. Response to the Office action filed on 03/08/04 is acknowledged. No amendment to the claims or specification was filed. Claims 1-53 are pending in the application. Claims 1-9 and 28-30 are elected with traverse. Claims 10-27 and 31-53 are withdrawn from consideration.

In response to the Applicant's arguments regarding restriction requirements, the examiner would like to indicate that the inventions are grouped as it was established in the previous Office action. Not only do they require a different search, but also a different examination, which is a burden for the examiner. Regarding specifically Groups I and II, which are "classified in the same class", as indicated by the Applicants, the examiner would like to notice that class 422 contains 77,977 US patents (with subclasses 24 and 46 containing 1,028 US patents); and therefore classification of different inventions in the same class cannot be an argument for the lack of burden for the examiner. Therefore, the Applicants' arguments regarding restriction requirements are not persuasive, and the restriction is made FINAL.

Response to Remarks (First Part)

2. Since no amendment was filed and the Applicants' arguments are not persuasive (see below), the rejections remain the same as established in the previous Office action.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not being written "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the invention in its best mode.

The specification discloses a numerous possible variations of sensors for dialysis system, which do not comprise clear and unambiguous embodiments due to too many possibilities for

different arrangements of the sensors and potential analytes. It is difficult to understand what exactly the embodiments disclose, except for the ammonia sensor depicted on Figures 1-8.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-7, 9 and 28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (US 4,661,246, IDS) in view of Khalil et al. (WO 01/35057 A2, IDS).

Ash discloses an ammonia sensor in dialysis system, comprising a fluid flow path, which is a portion of a dialysis system flow path, with an optical window 80, an ammonia test strip 78 comprising pH reagent and changing color when interacting with ammonia, and an optical reader

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77 outside the flow path, which identifies the change of the strip, and a processor 66. The strip is illuminated by a red-wavelength LED 76.

Ash does not specifically disclose pH sensitive hydrophobic membrane, a fluid pH conditioner or three color emitters connected to the processor.

Khali discloses "ammonia detection and measurement device", comprising Teflon (PTFE) hydrophobic membrane with pH sensitive reagent, which changes color upon reaction with ammonia. Khali emphasizes the preferences of such membrane since "the hydrophobicity of the PTFE provides a strong non-covalent bond to bond the dyes" (page 4, lines 19-23). Upon testing the prototype sensor "a buffered solution of ammonium chloride is made up at a known pH. From the known pKa and concentration of a NH₄Cl solution, one can predict the ammonia concentration in equilibrium with the solution" (page 6, lines 1-5). Khali further discloses different dye compositions for the membrane sensor, which may give absorbance in different spectral range.

It would have been obvious for anyone of ordinary skill in the art to substitute the paper pH indicator employed in Ash's sensor with Khali's hydrophobicity membrane exactly for the reasons indicated by Khali, i.e. because such membrane is much more stable and durable indicator than the paper strip. It would have been obvious to use the fluid pH conditioner to avoid changing pH of the fluid which is not caused by the presence of ammonia, as taught by Khali.

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash in view of Khalil, as applied to claims 1-7, 9 and 28-30 above, and further in view of Robinson et al. (US 4,350,660).

Although Ash in view of Khalil do not specifically disclose two color emitters connected to the processor, Khalil teaches various compositions for ammonia membrane sensor, which absorb in different visible ranges upon contacting ammonia. It would have been obvious for anyone of ordinary skill in the art to use two different color emitters in order to cover possible absorbance ranges for sensor membranes with various dye compositions.

Ash in view of Khalil do not specifically disclose an infrared emitter connected to the processor.

Robinson discloses infrared emitter for calibrating ammonia gas background (col. 2, lines 5-10).

It would have been obvious for anyone of ordinary skill in the art to use IR emitter in Ash-Khali's method for the same reason Robinson used it in his ammonia sensor - to pre-calibrate the readings of the ammonia sensor by taking into account the absorbing background of the fluid.

Response to Arguments

8. Applicant's arguments filed 03/08/04 have been fully considered but they are not persuasive. Regarding objection to the specification, it is worth noting that International Search Report to the corresponding PCT application from independent European patent examiner contains the following comments: "present claims 1-53 relate to a large number of possible devices and methods. In fact, the claims contain so many options, variables, possible permutations and provisos that a lack of clarity and conciseness within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible. Consequently, the search has been carried out for those parts of the application, which do appear to be clear and concise, namely claims 1-9 and 31-38. The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter, which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure". The specification of the instant disclosure in its major part is written in the same language as the claims, which were found non-searchable by the European patent examiner. It looks like these comments are the best arguments supporting the present examiner's position regarding the specification.

Regarding arguments related to the rejection over the prior art, it appears that the Applicants attack each of the combined references separately. Thus, they point out that Ash does not disclose a pH sensitive hydrophobic membrane. This is an absolutely correct statement,

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which also is expressed by the examiner in the previous Office action. Therefore, there was not attempt to use Ash's reference "on its own", contrary to what is argued by the Applicants. Ash is used in combination with Khali, who discloses a durable ammonia-sensitive dye-saturated microporous Teflon membrane. However, the Applicants raised the question regarding this combination, which is not clear to the examiner. The Applicants ask, "why then would one skill in the art be inclined to combine the teachings of Ash with Khali where Ash merely utilizes a test strip *in contrast* (?) to the ammonia-sensitive indicator dye as disclosed in Khali". It is difficult to understand, what the Applicants mean by the expression "in contrast" in this context. Ash is using the paper indicator strip, while Khali is using durable membrane indicator saturated with dye, with all the advantages of such membrane explicitly emphasized by Khali. What more motivation for using Khali's indicator membrane specific for ammonia in Ash's sensor can be expected by any routineer in the art? Also, it is not clear, what is the difference between dye-saturated Teflon membrane having microporous structure with dye molecules non-covalently attached to the membrane, and the membrane of the instant application? The examiner submits a reference from BHA Group, with a photograph of expanded Teflon membrane showing its microporous structure (using by BHA as a dust filter). The arguments regarding additional Robinson's reference are not clearly expressed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
3/23/04

A handwritten signature in black ink, appearing to read "Yelena Gakh".